

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of Blank et al. Serial No.: To be assigned Filed: January 21, 2004 For: PROTEIN RECOVERY	Group Art Unit: To be assigned Examiner: To be assigned CUSTOMER NO: 09157 Express Mail No: EV 351931692 US Mailed January 21, 2004
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INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants submit herewith patents, publications or other information (attached hereto and listed on the attached revised Form PTO-1449) of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR §1.56.

This Information Disclosure Statement is filed in accordance with the provisions of:

☒ **37 CFR §1.97(b)**

- within three months of the filing date of the application other than a continued prosecution application under 37 CFR §1.53(d); **or**
- within three months of the date of entry of the national stage of a PCT application as set forth in 37 CFR §1.491, **or**
- before the mailing of the first Office action on the merits; **or**
- before the mailing of the first Office action after the filing of a request for a continued examination under 37 CFR §1.114.

☐ **37 CFR §1.97(c)**

- by the applicant after the period specified in 37 CFR §1.97(b), but prior to the mailing date of any of a final action under 37 CFR §1.113, or a notice of allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application, and is accompanied by either the fee set forth in 37 CFR §1.17(p) **or** a statement as specified in 37 CFR §1.97(e), as checked below.

☐ **37 CFR §1.97(d)**

- after the period specified in CFR §1.97(c), and is accompanied by the fee set forth in 37 CFR §1.17(p) **and** a statement as specified in 37 CFR §1.97(e), as checked below.

(If either of boxes 37 CFR §1.97(c) or 37 CFR §1.97(d) is checked above, the following statement under 37 CFR §1.97(e) may need to be completed.)

- ☐ **37 CFR §1.97(e)** Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.
- ☐ **37 CFR §1.704(d)** Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and the communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of this information disclosure statement. Therefore, in accordance with the provisions of 37 CFR §1.704(d), the filing of this information disclosure statement will not be considered a failure to engage in reasonable efforts to conclude prosecution under 37 CFR §1.704.
- ☐ The U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR §1.17(p). Any deficiency or overpayment should be charged or credited to this deposit account.

A list of the patent(s) or publication(s) is set forth on the attached revised Form PTO-1449 (Modified).

A copy of the items on PTO-1449 is supplied herewith.

Those patent(s) or publication(s) which are marked with an asterisk (*) in the attached PTO-1449 form are not supplied because they were previously cited by or submitted to the Office in a prior application Serial Nos. 09/097,309, 09/460,587, and 09/940,166, filed 12 June 1998; 14 December 1999 and 27 August 2001 and relied upon in this application for an earlier filing date under 35 USC §120.

A concise explanation of relevance of the items listed on PTO-1449 is:

☒ not given

☐ given for each listed item

☐ given for only non-English language listed item(s) (Required)

- 0 in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references.

In accordance with 37 CFR §1.97(g), the filing of this information disclosure statement shall not be construed as a representation that a search has been made.

In accordance with 37 CFR §1.97(h), the filing of this information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 CFR § 1.56(b).

The Commissioner is hereby authorized to charge any additional fees required under 37 CFR 1.16 and 1.17 for this Information Disclosure Statement, or credit overpayment to Deposit Account No. 07-0630. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

GENENTECH, INC.

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FORM PTO-1449

U.S. Dept. of Commerce
Patent and Trademark Office

Atty Docket No.

P1105R1D1C2

Serial No.

Applicant

Blank et al.

Filing Date

21 Jan 2004

Group

LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

U.S. PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Name	Class	Subclass	Filing Date
	* 1	4,007,113	08.02.77	Ostreicher, E.A.			
	* 2	4,305,782	15.12.81	Ostreicher et al.			
	* 3	4,604,208	05.08.86	Chu et al.			
	* 4	4,676,980	30.06.87	Segal et al.			
	* 5	4,816,567	28.03.89	Cabilly et al.			
	* 6	4,849,352	18.07.89	Sullivan et al.			
	* 7	5,115,101	19.05.92	Bloom, J. W. et al.			
	* 8	5,429,746	04.07.95	Shadle et al.			
	* 9	5,470,954	28.11.95	Neslund, G. G. et al.			
	*10	5,534,615	09.07.96	Baker et al.			
	*11	5,591,828	07.01.97	Bosslet, K. et al.			
	*12	6,121,022	19.09.00	Presta, et al.			
	*13	6,322,997	27.11.01	Blank et al.			

FOREIGN PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Country	Class	Subclass	Translation Yes No
	*14	0,003,089 A1	25.07.79	EPO (ENGLISH ABSTRACT ATTACHED)			
	*15	127,737	12.12.84	EPO			
	*16	3-505283	21.11.91	JP			
	*17	5-502587	13.05.93	JP			
	*18	7-501698	23.02.95	JP			
	*19	93/11161	10.06.93	PCT			
	*20	WO 90/11814	18.10.90	PCT			
	*21	WO 91/00360	10.01.91	PCT			
	*22	WO 92/20373	26.11.92	PCT			
	*23	WO 93/08829	13.05.93	PCT			
	*24	WO 93/11162	10.06.93	PCT			
	*25	WO 93/16185	19.08.93	PCT			
	*26	WO 94/04690	03.03.94	PCT			
	*27	WO 96/27011	06.09.96	PCT			

OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

	*28	Brennan et al., "Preparation of bispecific antibodies by chemical recombination of monoclonal immunoglobulin G ₁ fragments" <u>Science</u> 229:81-83 (July 1985)
	*29	Bruggemann et al., "Designer Mice: The Production of Human Antibody Repertoires in Transgenic Animals" <u>Year in Immunology</u> 7:33-40 (1993)
	*30	Carter et al., "High Level Escherichia coli Expression and Production of a Bivalent Humanized Antibody Fragment." <u>Bio/Technology</u> , 10(2):163-167 (Feb 1992)

Examiner

Date Considered

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 LIST OF DISCLOSURES CITED BY APPLICANT (Use several sheets if necessary)		U.S. Dept. of Commerce Patent and Trademark Office		Atty Docket No. P1105R1D1C2	Serial No.
				Applicant Blank et al.	
				Filing Date 21 Jan 2004	Group
OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)					
*31	Carter et al., "Humanization of an Anti-p185 ^{HER2} Antibody For Human Cancer Therapy" <u>Proc. Natl. Acad. Sci. USA</u> 89:4285-4289 (May 1992)				
*32	Clackson et al., "Making Antibody Fragments Using Phage Display Libraries" <u>Nature</u> 352:624-628 (1991)				
*33	Clezardin, "One-step procedure for the rapid isolation of mouse monoclonal antibodies and their antigen binding fragments by fast protein liquid chromatography on a mono Q anion-exchange column" <u>Journal of Chromatography</u> 319:67-77 (1985)				
*34	Duchosal et al., "Immunization of hu-PBL-SCID mice and the rescue of human monoclonal Fab fragments through combinatorial libraries" <u>Nature</u> 355(6357):258-262 (Jan 16, 1992)				
*35	Gruber et al., "Efficient Tumor Cell Lysis Mediated by a Bispecific Single Chain Antibody Expressed in Escherichia Coli" <u>Journal of Immunology</u> 152:5368-5374 (1994)				
*36	Hildreth et al., "The Human Lymphocyte Function-Associated (HLFA) Antigen and a Related Macrophage Differentiation Antigen (HMac-1): Functional Effects of Subunit-Specific Monoclonal Antibodies" <u>The Journal of Immunology</u> 134:3272-3280 (1985)				
*37	Holliger et al., "Diabodies": Small Bivalent and Bispecific Antibody Fragments." <u>Proc. Natl. Acad. Sci. USA</u> 90:6444-6448 (Jul 1993)				
*38	Jakobovits et al., "Analysis of Homozygous Mutant Chimeric Mice: Deletion of the Immunoglobulin Heavy-Chain Joining Region Blocks B-cell Development and Antibody Production" <u>Proc. Natl. Acad. Sci. USA</u> 90:2551-2555 (March 1993)				
*39	Jakobovits et al., "Germ-line Transmission and Expression of a Human-Derived Yeast Artificial Chromosome" <u>Nature</u> 362:255-258 (March 18, 1993)				
*40	Kostelny et al., "Formation of a Bispecific Antibody by the Use of Leucine Zippers" <u>Journal of Immunology</u> 148(5):1547-1553 (1992)				
*41	Landschulz et al., "The Leucine Zipper: A Hypothetical Structure Common to a New Class of DNA Binding Proteins" <u>Science</u> 240:1759-1764 (1988)				
*42	Landschulz et al., "The Leucine Zipper: A Hypothetical Structure Common to a New Class of DNA Binding Proteins." <u>Science</u> 240:1759-1764 (Jun 1988)				
*43	Lindmark et al., "Binding of Immunoglobulins to Protein A and Immunoglobulin Levels in Mammalian Sera." <u>J. Immunol. Meth.</u> 62:1-13 (1983)				
*44	Marks et al., "By-Passing Immunization: Building High Affinity Human Antibodies by Chain Shuffling" <u>Bio/Technology</u> 10:779-783 (1992)				
*45	Marks et al., "By-Passing Immunization: Human Antibodies From V-gene Libraries Displayed On Phage" <u>J. Mol. Biol.</u> 222:581-597 (1991)				
*46	McCafferty et al., "Phage antibodies: filamentous phage displaying antibody variable domains" <u>Nature</u> 348:552-554 (1990)				
*47	Milstein and Cuello, "Hybrid Hybridomas and Their Use in Immunohistochemistry" <u>Nature</u> 305:537-540 (Oct 1983)				
*48	Morimoto et al., "Single-step purification of F(ab') ₂ fragments of mouse monoclonal antibodies (immunoglobulins G1) by hydrophobic interaction high performance liquid chromatography using TSKgel Phenyl-5PW" <u>Journal of Biochemical and Biophysical Methods</u> 24:107-117 (1992)				
*49	Morrison et al., "Chimeric Human Antibody Molecules: Mouse Antigen-Binding Domains with Human Constant Region Domains" <u>Proc. Natl. Acad. Sci. USA</u> 81:6851-6855 (November 1984)				
*50	O'Shea et al., "Preferential heterodimer formation by isolated leucine zippers from fos and jun" <u>Science</u> 245(4918):646-648 (Aug 11, 1989)				
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				Applicant Blank et al.	
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OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)					
*51	Pluckthun., "Antibodies From Escherichia coli." <u>The Pharmacology of Monoclonal Antibodies: Handbook of Experimental Pharmacology</u> , Rosenberg and Moore, eds., Berlin:Springer-Verlag, Chapter 11, Vol. 113:269-315 (1994)				
*52	Presta et al., "Humanization of an Antibody Directed Against IgE" <u>J. Immunol.</u> 151(5):2623-2632 (September 1, 1993)				
*53	Reif et al., "Characterization and application of strong ion-exchange membrane adsorbers as stationary phases in high-performance liquid chromatography of proteins" <u>Journal of Chromatography A</u> 654:29-41 (1993)				
*54	Sahni et al., "Proteosynthetic activity of immobilized Staphylococcus aureus V8 protease: application in the semisynthesis of molecular variants of α -globin" <u>Analytical Biochemistry</u> 193(2):178-185 (Mar 2, 1991)				
*55	Shalaby et al., "Development of Humanized Bispecific Antibodies Reactive with Cytotoxic Lymphocytes and Tumor Cells Overexpressing the HER2 Protooncogene" <u>Journal of Experimental Medicine</u> 175:217-225 (Jan 1, 1992)				
*56	Suresh et al., "Bispecific Monoclonal Antibodies from Hybrid Hybridomas" <u>Methods in Enzymology</u> 121:210-228 (1986)				
*57	Traunecker et al., "Bispecific Single Chain Molecules (Janusins) Target Cytotoxic Lymphocytes on HIV Infected Cells" <u>EMBO Journal</u> 10(12):3655-3659 (1991)				
*58	Tso et al., "Preparation of a Bispecific F(ab')/sub2/nor Targeted to the Human IL-2 Receptor" <u>Journal of Hematotherapy</u> 4:389-394 (1995)				
*59	Tutt et al., "Trispecific F(ab') ₃ Derivatives That Use Cooperative Signaling Via the TCR/CD3 Complex and CD2 to Activate and Redirect Resting Cytotoxic T Cells" <u>J. Immunol.</u> 147(1):60-69 (1991)				
*60	Voyksner et al., "Optimization of immobilized enzyme hydrolysis combined with high-performance liquid chromatography/thermospray mass spectrometry for the determination of neuropeptides" <u>Analytical Biochemistry</u> 188(1):72-81 (Jul 1990)				
*61	Waterhouse et al., "Combinatorial infection and in vivo recombination: a strategy for making large phage antibody repertoires" <u>Nucleic Acids Research</u> 21:2265-2266 (1993)				
*62	Zapata et al., "Engineering Linear F(ab') ₂ Fragments For Efficient Production in Escherichia coli and Enhanced Antiproliferative Activity" <u>Protein Engineering</u> 8(10):1057-1062 (1995)				
Examiner				Date Considered	
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